DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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BIOFIRE DIAGNOSTICS, LLC
KRISTEN KANACK, Ph.D.
VICE PRESIDENT OF REGULATED PRODUCTS
390 WAKARA WAY
SALT LAKE CITY UT 84108

January 30, 2015

Re: K143178
Trade/Device Name: FilmArray 2.0
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: NSU
Dated: October 31, 2014
Received: November 4, 2014

Dear Dr. Kanack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143178

Device Name
FilmArray 2.0

Indications for Use *(Describe)*
The FilmArray 2.0 is an automated in vitro diagnostic (IVD) device designed for use with FilmArray panels. The FilmArray 2.0 is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software automatically determines the results and provides a test report.

The FilmArray 2.0 is composed of one to eight instruments connected to a computer running FilmArray 2.0 software, which controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
BioFire Diagnostics, LLC

FilmArray® 2.0

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

BioFire Diagnostics, LLC
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Telephone: 801-736-6354
Facsimile: 801-588-0507

Contact: Kristen Kanack, ext. 330

Date Submitted: October 31, 2014

Device Name and Classification:

Trade Name: FilmArray 2.0

Regulation Number: 21 CFR 862.2570

Classification Name: Instrumentation for clinical multiplex test systems

Predicate Device:

K103175 – FilmArray

Intended Use:

The FilmArray 2.0 is an automated in vitro diagnostic (IVD) device designed for use with FilmArray panels. The FilmArray 2.0 is intended for use in combination with assay specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The software automatically determines the results and provides a test report.

The FilmArray 2.0 is composed of one to eight instruments connected to a computer running FilmArray 2.0 software, which controls the function of each instrument and collects, analyzes, and stores data generated by each instrument.

Device Description:

The FilmArray 2.0 is an automated *in vitro* diagnostic (IVD) device designed to work with specific FilmArray reagent panels to detect multiple nucleic acid targets contained in clinical specimens. The FilmArray 2.0 instrument interacts with a reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray 2.0 software automatically determines the results and provides a test report.

The FilmArray 2.0 permits up to eight instruments to connect to one computer. This configuration reduces the space requirements for the system and offers centralized data management. Accessories for the FilmArray 2.0 include a computer, computer stand and printer, a barcode scanner, an external Ethernet switch that allows several instruments to connect to a single computer, and an optional modular rack system to stack two instruments.

The main functions of the FilmArray 2.0 are as follows:

- Moving liquids within the pouch and delivering rehydrated reagents in a specified sequence to drive the nucleic acid purification and PCR amplification reactions.
- Heating and cooling to drive the PCR reactions and DNA melting.
- Capturing and processing of fluorescence images for analysis by the software.
- Automated data interpretation and test report generation.

Principles of Operation:

A test is initiated by loading Hydration Solution into one port of the FilmArray pouch and a patient sample mixed with the provided Sample Buffer into the other port of a FilmArray pouch and placing it in the FilmArray instrument. The pouch contains all of the reagents required for specimen testing and analysis in a freeze-dried format; the addition of Hydration Solution and Sample/Buffer Mix rehydrates the reagents. After the pouch is prepared, the software guides the user though the steps of placing the pouch into the instrument, scanning the pouch barcode, entering the sample identification, and initiating the run.

The FilmArray 2.0 instrument contains a coordinated system of inflatable bladders and seal points, which act on the pouch to control the movement of liquid between the pouch blisters. When a bladder is inflated over a reagent blister, it forces liquid from the blister into connecting channels. Alternatively, when a seal is placed over a connecting channel it acts as a valve to open or close a channel. In addition, electronically controlled pneumatic pistons are positioned over multiple plungers in order to deliver the rehydrated reagents into the blisters at the appropriate times. Two Peltier devices control heating and cooling of the pouch to drive the PCR reactions and the melt curve analysis.

Nucleic acid extraction occurs within the FilmArray pouch using mechanical and chemical lysis followed by purification using standard magnetic bead technology. The instrument has a built-in

bead-beater to aid in mechanical lysis and a retractable magnet that is used to capture the magnetic beads used in the nucleic acid purification process. After extracting and purifying nucleic acids from the unprocessed sample, a nested multiplex PCR is executed in two stages. During the first stage, a single, large volume, highly-multiplexed PCR reaction is performed (including reverse transcription of RNA to DNA, when needed). The products from first stage PCR are then diluted and combined with a fresh, primer-free master mix and a fluorescent double stranded DNA binding dye (LC Green® Plus, BioFire Defense). The solution is then distributed to each well of the array. Array wells contain sets of primers designed specifically to amplify sequences internal to the PCR products generated during the first stage PCR reaction. The 2nd stage PCR, or nested PCR, is performed in singleplex fashion in each well of the array. At the conclusion of the 2nd stage PCR, the array is interrogated by melt curve analysis for the detection of signature amplicons denoting the presence of specific targets. A digital camera placed in front of the 2nd stage PCR captures fluorescent images of the PCR reactions and software interprets the data.

The software automatically interprets the results of each DNA melt curve analysis and combines the data with the results of the internal pouch controls to provide a test result for each organism on the reagent panel.

Substantial Equivalence:

The FilmArray 2.0 is substantially equivalent to the current FilmArray device. The current FilmArray was cleared as a system with the FilmArray Respiratory Panel on February 17, 2011 under 510(k) K103175 and was determined to be a Class II device.

The following tables compare the FilmArray 2.0 to the current FilmArray device. Table 1 outlines the similarities and differences between the two devices.

Table 1. Comparison between FilmArray 2.0 and the Current FilmArray Device.

Element	Predicate: FilmArray (K103175)	New Device: FilmArray 2.0
Intended Use	The FilmArray instrument is an automated *in vitro* diagnostic (IVD) device designed to work with specific reagent pouches to detect multiple nucleic acid targets contained in clinical specimens. The instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The FilmArray software then automatically interprets the results and provides an easy-to-understand test report. The FilmArray device is composed of the FilmArray instrument and a laptop computer loaded with FilmArray software. The instrument contains a series of pneumatic actuators that move liquid within the pouch, a bead beater for disrupting the specimen during nucleic acid purification, two Peltier devices to drive thermocycling and DNA melting, and an optics system for detecting fluorescent signals. The FilmArray software controls the function of the instrument and collects, stores, and analyzes data generated by the instrument.	Same
Assays	For use with FDA cleared FilmArray panels: Respiratory Panel (RP) Blood Culture Identification (BCID) Panel Gastrointestinal (GI) Panel	Same
Protocol Processing Steps	Cell disruption, nucleic acid extraction, PCR1 thermocycling, PCR2 thermocycling, DNA melt and signal detection.	Same
Time to result	Approximately 1 hour per sample	Same
Technological Principles	Nested multiplex nucleic acid amplification (including reverse transcription as appropriate) followed by high-resolution melting analysis to confirm the identity of the amplified product.	Same

Element	Predicate: FilmArray (K103175)	New Device: FilmArray 2.0
Required Accessory	FilmArray reagent pouch	Same
Sample Preparation Method	Minimal sample processing and hands-on time.	Same
Test Interpretation and Results Reporting	Automated test interpretation and report generation. User cannot access raw data. Report can be printed.	Same
User Complexity	Moderate	Same
Instrument Optics	Charge-coupled device (CCD) camera. Soft-coated filters.	Complimentary metal-oxide semiconductor (CMOS) camera Hard-coated filters.
Instrument – Software Communication	Communication travels via Firewire and USB cables/ports.	Communication travels via Ethernet cable/port. Communication for multiple instruments mediated by a multi-port switch.
Device configuration	One FilmArray instrument to one laptop computer with mouse, barcode scanner and pouch loading station. Single-sample test capacity. Printer optional. Instrument held at 0° angle.	Up to eight FilmArray 2.0 instruments to one computer with mouse, barcode scanner and pouch loading station. Single-sample test capacity per instrument with random-access multi-sample test capacity per system. Printer provided with the system. Interlocking two-instrument racks available to stack instruments and reduce system footprint. (Optional) Instrument held at 0° angle when no rack is used. Instrument held at 15° angle on rack.

Summary of Performance Data:

The performance of the FilmArray 2.0 was evaluated using three FDA cleared FilmArray Panels (Respiratory Panel (RP), Blood Culture Identification (BCID) Panel, and Gastrointestinal (GI) Panel). Each panel was evaluated in three studies, a clinical specimen comparison study, a low analyte study, and a reproducibility study. The clinical comparison study involved testing a set

of clinical samples using both the current FilmArray and FilmArray 2.0. The low analyte study compared the performance of the two devices by testing contrived samples spiked around the previously-determined limit of detection (LoD) for each assay on the panel. The reproducibility study was conducted using multi-instrument FilmArray 2.0 systems and involved testing of a set of well-characterized contrived samples at three different testing sites over several days and comparing the results to those previously obtained with the current FilmArray device. In all studies (i.e., detection in clinical specimens, detection of low analyte levels, and reproducibility) the performance of all three panels was found to be equivalent on the previously cleared FilmArray and the FilmArray 2.0. Data generated in these studies are presented in three concurrently-submitted 510(k) premarket notifications.